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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,320	05/10/2007	Noriaki Kato	868_012	4731

25191 7590 09/27/2010

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EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
09/27/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/587,320	**Applicant(s)** KATO ET AL.	
	Examiner Nissa M. Westerberg	**Art Unit** 1618	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 September 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Nissa M Westerberg/
Examiner, Art Unit 1618

Continuation of 11. does NOT place the application in condition for allowance because: Claims 10 - 12, 14 and 18 - 21 were rejected under 35 U.S.C. 103 (a) as being unpatentable over Mylari (US 6,426,341) in views of Crary et al. (US 5,639,482). This rejection is MAINTAINED for the reasons of record set forth in the Office Actions mailed March 10, 2010 and June 21, 2010 and those set forth below.

Claims 10 - 12, 14 and 18 - 21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Akita et al. (Acta Med Okayama) in view of Crary (US 5,639,482) and Wani et al. (JK Practitioner 2003) This rejection is MAINTAINED for the reasons of record set forth in the Office Actions mailed March 10, 2010 and June 21, 2010 and those set forth below.

Applicants arguments regarding the Crary reference, utilized as a secondary reference in both of the above rejections, is that the term "diabetic complications" used by the Examiner is not found In Crary who uses the phrase "the complications of capillary leakage and bleeding in the diabetic" is used instead (e.g., col 3, ln 4 - 5). This term is used in a limited context that defines the clinical features of diabetic retinopathy while the phrase "diabetic complications" is a comprehensive term that induces neuropathy, nephropathy or retinopathy. Also, the phrase "decrease complications from diabetes" is also not found in the Crary. These arguments are unpersuasive. Crary is directed to particular species within the genus of diabetic complications - diabetic retinopathy and macular edema of diabetic retinopathy. Thus, the composition of Crary decreases diabetic complications. It is also noted that the sentence in which the phrase "diabetic complications" was used was not only referring to the compositions of Crary but also ARIs such as SNK-860.

Applicants also argue that that it is not necessarily the case that compound showing an effect on diabetic retinopathy is also useful for diffuse macular edema in diabetic patients. In addition to the evidence already of record, Applicants provide papers discussing that calcium dobesilate significantly ameliorates diabetic retinopathy but neither prevents the occurrence or reduces the development of macular edema. PKC-beta reduced the progression of macular edema in diabetic patients but did not prevent the progression of diabetic retinopathy. "This evidence clearly proves that, while some agents are useful for both retinopathy and macular edema, others are useful for only one disease." Applicants cannot accept the conclusion of the Examiner based only on the statements of Crary. These arguments are unpersuasive. To establish a prima facie case of obviousness, only a reasonable expectation, not absolute predictability, of success is required. The applied prior art establishes that the person of ordinary skill in the art would have reasonable expectation of success that administration of the compound of the instant claim 12 (called fidarestat in Mylari and SNK-860 in Akita et al.) would ameliorate the diabetic diffuse macular edema when administered to a subject having diabetic diffuse macular edema. Mylari and Akita et al. disclose that administration of the instantly claimed compound ameliorates various complications that occur with diabetics including changes in the eye and Crary et al. discloses that some agents are able to treat both diabetic retinopathy and diffuse macular edema of human diabetic retinopathy.